

Notice of Allowability

Application No.

10/754,541

Examiner

Michael P. Barker

Applicant(s)

URANO ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/28/06.
2. ☒ The allowed claim(s) is/are 1,3-8,10,12-39.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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DETAILED ACTION

The restriction requirement is withdrawn; the previously withdrawn claims are rejoined. Applicant's amendments overcome the 35 U.S.C. 102 rejections; the objection is withdrawn. Applicant amended **Claims 10, 12-14, 16-21, 23-28, and 30-39** by Examiner's Amendment, *infra*. **Claims 1, 3-8, 10, and 12-39** are pending and in condition for allowance.

Restriction/Election

The restriction requirement, made final February 6, 2006, is withdrawn, and **Claims 16, 17, 23, 24, 30, 31, 37, and 38** are rejoined.

Remarks/Arguments Document

In regard to the Remarks/Arguments Document filed April 28, 2006, the amendments to the Claims overcome the 35 U.S.C. 102(a), 102(e), and 112 2d paragraph rejections made in the February 6, 2006 Office Action.

The objection is withdrawn as to **Claim 8**.

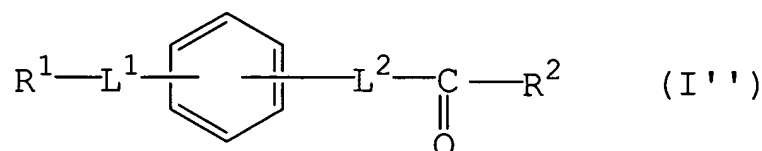
Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

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Authorization for this examiner's amendment was given in a telephone interview with Thomas Cunningham on July 5, 2006. The application has been amended as follows:

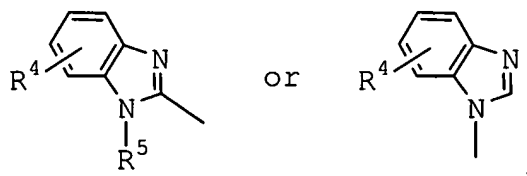
1. **Claim 10 (Currently Amended):** A compound having the following formula (I''):



wherein

wherein

R^1 is an N-containing condensed heterocyclic ring represented by the following formula:



wherein

R^4 is hydrogen or a group selected from the group consisting of lower alkyl and aryl, and

R^5 is hydrogen or a group selected from the group consisting of lower alkyl and aryl(lower)alkyl,

R^2 is hydroxyamino,

L^1 is $-(\text{CH}_2)_n-$ (wherein n is 1 or 2) optionally substituted with aryl(lower)alkyl, and

L^2 is vinylene;

or a salt thereof..

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2. **Claim 12** (Currently Amended): A composition comprising: the compound of claim 1 in an amount sufficient to inhibit histone deacetylase, and a pharmaceutically acceptable carrier or excipient.

3. **Claim 13** (Currently Amended): A pharmaceutical composition comprising the compound of claim 1 which composition is in a solid form ~~in an amount effective for treating or preventing an inflammatory disorder, diabetes, diabetic complications, homozygous thalassemia, fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), organ transplant rejection, an autoimmune disease, a protozoal infection or a tumor.~~

4. **Claim 14** (Currently Amended): A pharmaceutical composition comprising: the compound of claim 1 which composition is in a liquid form ~~as an active ingredient, in association with a pharmaceutically acceptable, substantially non-toxic carrier or excipient.~~

5. **Claim 16** (Currently Amended): A method for treating a disease or disorder caused by abnormal gene expression benefited by inhibiting histone deacetylase, comprising ~~using~~ administering an amount of the compound of claim 1 effective to inhibit histone deacetylase to a mammal in need thereof.

6. **Claim 17** (Currently Amended): A method for treating ~~or preventing~~ a disease or disorder associated with histone deacetylase selected from the group consisting of an ~~inflammatory disorder~~ inflammation, diabetes, diabetic complications, homozygous thalassemia, fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), organ transplant rejection, an

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~~autoimmune disease, and~~ a protozoal infection ~~or a tumor~~, which comprises administering an effective amount of the compound of claim 1 to a ~~subject~~ mammal in need thereof.

7. **Claim 18** (Currently Amended): A commercial package comprising:
the pharmaceutical composition of claim 13 and a written matter associated therewith, ~~the~~
~~written matter stating that the pharmaceutical composition may or should be used for treating or~~
~~preventing an inflammatory disorder, diabetes, diabetic complications, homozygous thalassemia,~~
~~fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), an organ transplant rejection, an~~
~~autoimmune disease, a protozoal infection or a tumor.~~

8. **Claim 19** (Currently Amended): A composition comprising: the compound of
claim 7 in an amount sufficient to inhibit histone deacetylase and a pharmaceutically acceptable
carrier or excipient.

9. **Claim 20** (Currently Amended): A pharmaceutical composition comprising an
amount of the compound of claim 7 which composition is in a solid form ~~effective for treating or~~
~~preventing an inflammatory disorder, diabetes, diabetic complications, homozygous thalassemia,~~
~~fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), organ transplant rejection, an~~
~~autoimmune disease, a protozoal infection or a tumor.~~

10. **Claim 21** (Currently Amended): A pharmaceutical composition comprising:
the compound of claim 7 which composition is in a liquid form ~~as an active ingredient, in~~
~~association with a pharmaceutically acceptable, substantially non-toxic carrier or excipient.~~

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11. **Claim 23** (Currently Amended): A method for treating a disease or disorder caused by abnormal gene expression benefited by inhibiting histone deacetylase, comprising using administering an amount of the compound of claim 7 effective to inhibit histone deacetylase to a mammal in need thereof.

12. **Claim 24** (Currently Amended): A method for treating ~~or preventing~~ a disease or disorder associated with histone deacetylase selected from the group consisting of an ~~inflammatory disorders~~ inflammation, diabetes, diabetic complications, homozygous thalassemia, fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), organ transplant rejection, ~~an autoimmune disease, and~~ a protozoal infection ~~or a tumor~~, which comprises administering an effective amount of the compound of claim 7 to a ~~subject~~ mammal in need thereof.

13. **Claim 25** (Currently Amended): A commercial package comprising: the pharmaceutical composition of claim 20, and a written matter associated therewith, ~~the written matter stating that the pharmaceutical composition may or should be used for treating or preventing an inflammatory disorder, diabetes, diabetic complications, homozygous thalassemia, fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), an organ transplant rejection, an autoimmune disease, a protozoal infection or a tumor.~~

14. **Claim 26** (Currently Amended): A composition comprising the compound of claim 8 in an amount sufficient to inhibit histone deacetylase, and a pharmaceutically acceptable carrier or excipient.

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15. **Claim 27** (Currently Amended): A pharmaceutical composition comprising the compound of claim 8 which composition is in a solid form in an amount effective for treating or preventing an inflammatory disorder, diabetes, diabetic complications, homozygous thalassemia, fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), an organ transplant rejection, an autoimmune disease, a protozoal infection or a tumor, which comprises the compound of claim 8.

16. **Claim 28** (Currently Amended): A pharmaceutical composition comprising: the compound of claim 8 which composition is in a liquid form as an active ingredient, in association with a pharmaceutically acceptable, substantially non-toxic carrier or excipient.

17. **Claim 30** (Currently Amended): A method for treating a disease or disorder caused by abnormal gene expression benefited by inhibiting histone deacetylase, comprising using administering an amount of the compound of claim 8 effective to inhibit histone deacetylase to a mammal in need thereof.

18. **Claim 31** (Currently Amended): A method for treating ~~or preventing an inflammatory disorder~~ inflammation, diabetes, diabetic complications, homozygous thalassemia, fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), organ transplant rejection, ~~an autoimmune disease, and~~ a protozoal infection ~~or a tumor~~, which comprises administering an effective amount of the compound of claim 8 to a mammal ~~subject~~ in need thereof.

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19. **Claim 32** (Currently Amended): A commercial package comprising:
the pharmaceutical composition of claim 27 and a written matter associated therewith,~~the~~
~~written matter stating that the pharmaceutical composition may or should be used for treating or~~
~~preventing an inflammatory disorder, diabetes, diabetic complications, homozygous thalassemia,~~
~~fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), an organ transplant rejection, an~~
~~autoimmune disease, a protozoal infection or a tumor.~~

20. **Claim 33** (Currently Amended): A composition comprising the compound of
claim 10 in an amount sufficient to inhibit histone deacetylase, and a pharmaceutically
acceptable carrier or excipient.

21. **Claim 34** (Currently Amended): A pharmaceutical composition comprising the
compound of claim 10 which composition is in a solid form ~~in an amount effective for treating or~~
~~preventing an inflammatory disorder, diabetes, diabetic complications, homozygous thalassemia,~~
~~fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), an organ transplant rejection, an~~
~~autoimmune disease, a protozoal infection or a tumor, which comprises the compound of claim~~
~~10.~~

22. **Claim 35** (Currently Amended): A pharmaceutical composition comprising:
the compound of claim 10 which composition is in a liquid form ~~as an active ingredient, in~~
~~association with a pharmaceutically acceptable, substantially non-toxic carrier or excipient.~~

23. **Claim 36** (Currently Amended): The composition of claim 33 in a form suitable
for intravenous or intramuscular administration.

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24. **Claim 37** (Currently Amended): A method for treating a disease or disorder associated with ~~inhibiting~~ histone deacetylase, comprising ~~using~~ administering an amount of the compound of claim 10 effective to inhibit histone deacetylase to a mammal in need thereof.

25. **Claim 38** (Currently Amended): A method for treating ~~or preventing~~ a disease or a disorder associated with histone deacetylase selected from the group consisting of an ~~inflammatory disorders~~ inflammation, diabetes, diabetic complications, homozygous thalassemia, fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), organ transplant rejection[s], ~~autoimmune diseases~~, and a protozoal infection ~~or tumors~~, which comprises administering an effective amount of the compound of claim 10 to a mammal ~~human being or an animal~~.

26. **Claim 39** (Currently Amended): A commercial package comprising: the pharmaceutical composition of claim 34, and a written matter associated therewith, ~~the written matter stating that the pharmaceutical composition may or should be used for treating or preventing an inflammatory disorder, diabetes, diabetic complications, homozygous thalassemia, fibrosis, cirrhosis, acute promyelocytic leukaemia (APL), an organ transplant rejection, an autoimmune disease, a protozoal infection or a tumor.~~

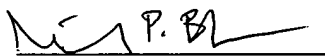
The amendments above, as well as the lack of prior art, render Applicant's invention ALLOWED.


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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael P. Barker
Patent Examiner, AU 1626

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

(for) Joseph McKane
Supervisory Patent Examiner, AU 1626